Darunavir/r versus Lopinavir/r in Treatment-Naïve

ARTEMIS Trial
### Once Daily Darunavir/r versus Lopinavir/r in Treatment-Naïve

**ARTEMIS: Study Design**

<table>
<thead>
<tr>
<th><strong>Study Design: ARTEMIS</strong></th>
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<tbody>
<tr>
<td><strong>Background:</strong> Randomized, open-label phase 3 trial comparing the efficacy and safety of once-daily darunavir/ritonavir with lopinavir/ritonavir in treatment-naïve patients with HIV infection</td>
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<td><strong>Inclusion Criteria (n = 689)</strong></td>
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<td>- Age ≥18</td>
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<td>- Antiretroviral-naïve patients</td>
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<td>- HIV RNA ≥5000 copies/mL</td>
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<tr>
<td>- No AIDS-defining illness</td>
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<td><strong>Treatment Arms</strong></td>
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<tr>
<td>- DRV 800 mg QD + RTV 100 mg QD + TDF-FTC</td>
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<tr>
<td>- LPV/r 800/200 mg QD (or 400 mg bid) + TDF-FTC</td>
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**ARTEMIS = AntiRetroviral Therapy with TMC114 ExaMined In naive Subjects**

Once Daily Darunavir/r versus Lopinavir/r in Treatment-Naïve ARTEMIS: Results at 48 Weeks

Week 48: Virologic Response (Intent-to-Treat Analysis)

**Conclusion**: “DRV/r 800/100 mg qd was non-inferior to LPV/r 800/200 mg at 48 weeks, with a more favorable safety profile. Significantly higher response rates were observed with DRV/r in patients with HIV-1 RNA at least 100,000 copies/ml. DRV/r 800/100 mg offers a new effective and well tolerated once-daily, first-line treatment option for treatment-naive patients.”
Once Daily Darunavir/r versus Lopinavir/r in Treatment-Naïve ARTEMIS: Results at 96 Weeks

Week 96: Virologic Response (Intent-to-Treat Analysis)

![Bar chart showing virologic response at Week 96 for Darunavir + Ritonavir + TDF/FTC and Lopinavir/ritonavir + TDF/FTC.]

**Baseline HIV RNA**

- **HIV RNA <50 copies/mL (%):**
  - All: 79 (Darunavir) vs 71 (Lopinavir), P = 0.012
  - <100,000 copies/mL: 81 (Darunavir) vs 75 (Lopinavir), P = 0.174
  - ≥100,000 copies/mL: 76 (Darunavir) vs 63 (Lopinavir), P = 0.023

Once Daily Darunavir/r versus Lopinavir/r in Treatment-Naïve ARTEMIS: Results at 96 Weeks

Week 96: Analysis of Lipids

Conclusion: “At week 96, once-daily DRV/r was both statistically noninferior and superior in virologic response to LPV/r, with a more favorable gastrointestinal and lipid profile, confirming DRV/r as an effective, well tolerated, and durable option for antiretroviral-naive patients.”

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